

BXTR 4021  
PATENT

REMARKS

Claims 1-17 and 23 will be pending in this case after entry of this amendment. Claim 1 is amended herein. Claims 2 and 18-22 are cancelled. New claim 24 is added. Claims 1, 3-17 and 23-24 are patentable for the reasons discussed below.

Entry of this amendment after final is appropriate because it raises no new issues. Claim 1 is amended to incorporate the requirements of claim 2 and new claim 24 is claim 1 with language added in view of the Examiner's comments in paragraph 14 of the final Office action mailed January 27, 2006.

i. Background

It is often important to be able to maintain (or possibly establish) aseptic or sterile conditions in polymeric tubing during connection of one piece of tubing to another. For example, there is often a need to connect polymeric tubing to deliver flowable food or medical products (e.g., those used for dialysis treatment). This has been done by cutting the tubing by melting it with a heated wafer or hot knife and then joining two ends together before they cool to melt seal the ends together. However, this type of method is unreliable because variations in the melting and cutting process, sometimes result in imperfect seals, leaks, or bacterial infiltrations. Even if the process works as designed, there is opportunity for contamination because the heated ends of the tubing sections are uncovered and exposed to the surrounding environment in the time between the cutting/melting and joining.

BXTR 4021  
PATENT

The applicants have solved the foregoing problem with their present invention. Briefly, two tubing sections to be joined are placed in opposed end-to-end relation so that the axially facing surfaces are free from exposure to the surrounding environment. After the ends of the tubing sections are placed together an electromagnetic beam (e.g., a laser beam) is used to weld the two tubing sections together. This way the axially facing surfaces of the tubing sections are not exposed to the environment after the heating of the ends of the tubing sections, thereby reducing the opportunity for contamination. Further, concerns about contamination of the tubing from before the placing of the ends of the tubing sections in opposed end-to-end relation are alleviated because the electromagnetic beam can sanitize (or sterilize) the ends of the tubing sections in the process of welding the tubing sections together.

ii. Claim 24

New Claim 24 is directed to a method of connecting together two sections of tubing, comprising the steps of:

"placing the two tubing sections in opposed, end-to-end relation so that axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment; and then directing an electromagnetic beam generally toward the location where the axially facing surfaces are in opposed, end-to-end relation and thereby welding the two sections of tubing together at the location, wherein the electromagnetic beam is directed toward the end of either of the two tubing sections to bring the axially facing surface of either tubing section above a melting temperature of a material of the tubing section only after the step of placing the two tubing sections in opposed, end-to-end relation so that

BXTR 4021  
PATENT

the axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment." (emphasis added).

The Examiner contends in paragraph 14 of the final Office action of January 27, 2006 that the previous claims did not require the electromagnetic beam to be applied to the tube ends only after they are placed in end-to-end relation. Claim 24 has been written to address this perceived omission. Claim 24 specifies that the electromagnetic beam is used to heat the ends of the two tubing sections only after the ends of the tubing sections are placed together in end-to-end relation. Support for claim 24 is in ¶¶ 14-15 and 40-42 of the original application. Placing the ends of the tubing section in opposed, end-to-end relation so their axially facing surfaces are free from exposure to the environment before heating the ends of the tubing sections is an efficient way to weld and sanitize the tubing sections at the same time with the electromagnetic beam.

In contrast, U.S. Patent App. Pub. No. 20030143352 (Yang et al.) teaches a method of connecting tubing in which the ends of tubes are first heated by a laser. After the ends are heated to a temperature high enough for fusion, the laser is shut off and then the tubes are brought together to form a weld. See ¶¶ 70-71. Yang, teaches that the laser may be energized "again" after the tubing sections are placed together. See ¶ 71. However, this would require the laser to be operated twice, making the method less efficient than the method recited in claim 1. Moreover, there is no disclosure or suggestion of a method where welding of the tubes occurs only after they are placed in end-to-end relation.

One important difference between the Yang method and method of claim 1 is that in the Yang method the axially facing surfaces at the

BXTR 4021  
PATENT

ends of the tubes are exposed to the environment between the initial heating of the tube sections by the laser and the time the ends of the tubes are brought together to form the weld. This creates the opportunity for contamination of the tubing. Although sealing the ends of the tubing sections, as described in Yang (paragraph 66), does free the inside of the tubing from exposure to the environment, it leaves the axially facing ends of the tubing (i.e., the exterior of the end of the sealed tubing section) exposed to the environment. Thus, sealing the ends of the tubing does not adequately protect against contamination on the axially facing ends of the sealed tubing sections.

Accordingly, claim 24 is submitted as patentable in that the prior art of record, including Yang, fails to teach or suggest a method of connecting tubing comprising the steps of first placing the ends of the tubes in end-to-end relation so that the axially facing surfaces are substantially free from exposure to the environment followed by directing a beam of electromagnetic radiation to the location at which the ends of the tubes are located to weld the tube sections together. Claim 24 should also be allowed in view of the Examiner's statements in paragraph 14 of the final Office action.

iii. Claims 1, 3-17, and 23

Amended claim 1 includes the limitations of original claim 2, which is cancelled herein. Claims 1, 3-17, and 23 are patentable because the prior art fails to show or suggest a method of connecting tubing sections comprising placing two tubing sections in opposed end-to-end relation so that the unmelted axially facing surfaces of the tube sections at the ends are free from exposure to the

BXTR 4021  
PATENT

surrounding environment and then directing an electromagnetic beam generally toward the ends of the tube sections to weld them together.

Claim 1 is directed to a method of connecting together two sections of tubing comprising:

"placing the two tubing sections in opposed, end-to-end relation so that axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment; and then

directing an electromagnetic beam generally toward the location where the axially facing surfaces are in opposed, end-to-end relation and thereby welding the two sections of tubing together at the location,

wherein during the step of placing the two tubing sections in opposed, end-to-end relation, the temperature of each of the tubing sections at the axial surfaces thereof is below the melting temperature of material forming the tubing section." (emphasis added).

The prior art, including Yang, fails to show or suggest the method of claim 1. In particular, the prior art fails to teach placing two tubing sections in opposed end-to-end relation so the axially facing surfaces thereof are free from exposure to the surrounding environment when their temperatures are below the melting point and then welding the two tubing sections together with an electromagnetic beam.

A reference does not anticipate a claimed invention unless every element of the claim is found therein. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP §2131. Yang does not teach that the ends of two tubing sections can be below the melting point when they are placed in end-to-end relation. On the contrary, Yang repeatedly teaches that the ends of the tubing are melted by a laser before they are placed in opposed end-to-end relation so the

BXTR 4021  
PATENT

axially facing surfaces are free from exposure to the environment. Yang explains: "As the laser beam strikes the sealed tube ends 51, the heating, melting and aseptic (and/or sterilization) process begins." Yang, ¶ 69 (emphasis added). Further, "As the temperature of the tubing material at the tube ends 51 increases, the tube ends begin to melt, flow and reopen." Id. at ¶ 71 (emphasis added). Also, "Once the heat sensors 320 detect that the required aseptic or sterilization temperature level is attained and sufficient melting of the tube ends has occurred the laser 200 shuts off." Id. (emphasis added). After melting the tube ends as described above, Yang explains: "At this point, the now melted and aseptically heated or sterilized end tubes 51 contact each other. A weld seal W is formed." Id. (emphasis added). Thus, Yang is explicit in its teaching that the ends of the tubes are melted before they are placed in opposed end-to-end relation so that the axially facing surfaces are free from exposure to the environment. There is no ambiguity regarding the state of the material at the tube ends. The ends must be sufficiently melted to form a "weld seal" when they are brought together.

Yang does describe a second embodiment in which the laser is energized after the tube ends are placed in opposed end-to-end relation. Yang ¶ 71. In particular, Yang explains: "In another embodiment, the laser unit 200 may be energized again." Id. (emphasis added). The use of the word "again" incorporates the immediately preceding description of the first embodiment, in which the laser is used to heat the tubes ends so they are melted when they are brought together, to describe the initial steps of the second embodiment. In other words, the tube ends were melted when they were brought into contact with each other in the second embodiment too. There is no basis for concluding that the tube ends are at less than their

BXTR 4021  
PATENT

melting temperature when they are brought into contact in the second embodiment. Yang is unambiguous in its teaching that the tube ends are melted when they contact each other. Yang describes that the initial heating by the laser is to a temperature sufficient for melting and aseptic and/or sterilization and that when the tube ends are brought together a weld seal is formed. Yang consistently uses the conjunction "and" rather than "or" to link melting to other results of the heating. See Yang ¶¶ 69-71. Whether or not it would be possible to sterilize the tube ends without melting is not material, because prior art does not render a claim unpatentable unless it contains each and every element of the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989); MPEP § 2131.

Applicants also note that the sealed ends of the tube ends, as described in Yang ¶ 66, have axially facing surfaces that are not free from exposure to the environment. A tube end can be sealed to free the inner radially facing surfaces of the tube ends from exposure to the environment, but the sealed tube end still has an axially facing surface (e.g., the part of the tube end facing the other tube with which it will be joined) that is exposed to the environment.

Accordingly, claim 1 is patentable in that the prior art, including Yang, fails to disclose a method of connecting tubing sections comprising placing two tubing sections in opposed end-to-end relation so that the unmelted axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment and then directing an electromagnetic beam generally toward the ends of the tube sections to weld them together. Claims 3-17 and 23 depend from claim 1 and are patentable for the same reasons.

BXTR 4021  
PATENT

iv. Claims 18-22

Claims 18-22 are cancelled herein without prejudice. Applicants disagree with the grounds for rejection of claims 18-22 set forth in the Office action, but have decided to cancel the claims in an effort to expedite allowance of other claims in the application. Applicants reserve the right to pursue patent protection to the subject matter of claims 18-22 in one or more subsequent patent applications claiming priority from this application.



BXTR 4021  
PATENT

**Conclusions**

Applicants respectfully request consideration and allowance of claims 1, 3-17, and 23-24 for the reasons discussed above. Applicants also requests the Examiner to telephone the undersigned for an interview if she finds that this amendment does not place the claims in condition for allowance.

The Commissioner is hereby authorized charge any government fees to Deposit Account No. 19-1345.

Respectfully submitted,



Kurt F. James, Reg. No. 33,716  
SENNIGER POWERS  
One Metropolitan Square, 16<sup>th</sup> Floor  
St. Louis, Missouri 63102  
(314) 231-5400

KFJ/NCW/cms